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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,096	09/26/2000	Linda S. Mansfield	MSU 4.1-526	7494

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EXAMINER
MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/670,096	MANSFIELD ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☒ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2 and 21*.
   Claim(s) withdrawn from consideration: _____.
8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☒ Other: *Form 892*

N. M. Minnifield
Primary Examiner
Art Unit: 1645

ADVISORY ACTION

1. Applicants' amendment filed April 28, 2003 is acknowledged and has been entered. Claims 3 and 22 have been canceled. Claims 1, 2 and 21 have been amended. Claims 1, 2 and 21 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment with the exception of those discussed below.

2. The rejection of claims 1 and 2 under 35 U.S.C. § 102(b) as anticipated by Liang et al, 1998 is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 1-3 under this statutory provision, as set forth in the last Office action.

Applicants' arguments filed April 28, 2003, have been fully considered but they are not deemed to be persuasive. Applicants have asserted that the currently amended claims claim compositions, which comprise a mixture of isolated antibodies against the 16 and 30 kDa antigens in a pharmaceutically acceptable carrier and wherein the antibodies are from serum from an animal inoculated with the antigen; and further that claim 2 consists essentially of a mixture of monoclonal antibodies against the 16 and 30 kDa antigens. Applicants have asserted that the prior art does not disclose such a composition. However, it is noted that the claimed invention is directed to compositions comprising a mixture of isolated antibodies against the 16 and 30 kDa antigens in a pharmaceutically acceptable carrier, which the prior art of Liang et al 1998 discloses. The recitation of "wherein the antibodies are from serum from an animal inoculated with the antigen" is viewed as a process limitation in a product claim, which does not impart novelty or unobviousness to an antibody when the same antibody is taught by the prior art.

3. The rejection of claim 21 under 35 U.S.C. § 112, first paragraph as not being enabled by the specification is maintained. This rejection is maintained for essentially the same reasons as the rejection of claims 21 and 22 under this statutory provision, as set forth in the last Office action.

Applicants' arguments filed April 28, 2003, have been fully considered but they are not deemed to be persuasive. The Murphy declaration under 37 CFR 1.132 filed April 28, 2003 is insufficient to overcome the rejection of claim 21 based upon 112, first paragraph as set forth in the last Office action. It is noted that the declaration set forth data results obtained from *in vitro* methods, not *in vivo* methods as the claimed invention recites. The declaration is not commensurate in

scope with the claimed invention. The declaration does not provide evidence that the claimed antibodies have been used in methods for treating (i.e. counteracting a disease, infection, or condition) an equine infected with *Sarcocystis neurona*, comprising administering in a pharmaceutically acceptable carrier antibodies against the 16 and 30 kDa antigens from *S. neurona*. Applicants have asserted that the Liang et al, 1998 only show that the antibody against the 16 kDa antigen is neutralizing and that the antibody against the 30 kDa antigen is non-neutralizing. Applicants have asserted in the declaration that their antibody against the 30 kDa antigen in neutralizing and that the combination of antibodies against the 16 and 30 kDa antigens are neutralizing. However, as previously stated this data is only obtained from *in vitro* methods and Liang et al 1998 also indicates that "[A]lthough *S. neurona* was sensitive to specific antibodies, a 10 min exposure to antiserum was required to yield a significant reduction in parasite production (data not shown). This may partially explain why protective antibodies to some apicomplexan parasites are effective in vitro but not in vivo." (p. 1837, col. 1). Further, Liang et al, 1998 disclose that the "parasite may express different proteins at different stages of in vivo or in vitro development; and some proteins may be expressed and function essentially only in vitro. Such proteins would be inappropriate targets for vaccine development." (p. 1837, col. 2). Applicants have not provided any evidence on the efficacy of these antibodies (antibodies against 16 and 30 kDa antigens) in treating infected equines.

4. No claims are allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N.M. Minnifield
Primary Examiner
Art Unit 1645

NMM
May 27, 2003